REMARKS

Claims 1-24, 27-33, and 35-42 are pending in this application. Claim 1 has been amended to add the phrase "so that the additive material coats the active particles". Support for this amendment can be found on page 12, lines 12-13, wherein the use of jet milling to achieve a coating of additive material is discussed in the context of the teaching in the prior art, which held that jet milling was not suitable for providing a coating of additive material on the surface of the active particles (page 11, lines 10-13); and on page 25, lines 17-23.

It is respectfully submitted that no new matter has been added by virtue of these amendments.

§ 102(b) as being anticipated by and 35 U.S.C. § 103(a) as being unpatentable over Curtet

In the Office Action, the Examiner rejected claims 1, 16-24, 27, 29-32, and 41-42 under 35 U.S.C. § 102(b) as being anticipated by Curtet et al. (U.S. Patent No. 4,895,726) (hereinafter "the Curtet patent"). The Examiner also rejected claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Curtet.

Claim 1 as amended, recites:

> A method for making composite active particles for pulmonary inhalation, the method comprising the step of jet milling active particles in the presence of particles of additive material so that the additive material coats the active particles.

In contrast to claim 1, the Curtet patent is entirely concerned with administration of hyperlipidemia and hypercholesterolemia drugs (column 1, lines 1-14), such as fenofibrate (column 1, lines 35-36), in the form of orally administered gelatine capsules (column 1, lines 13-14). The Curtet patent does not refer to, or disclose particles for pulmonary administration, as recited in claim 1 of the present application. Nor, in fact, does Curtet even disclose an active ingredient that would be suitable for administration to the lung. Accordingly, Curtet does not teach a method for making composite active particles for pulmonary inhalation in accordance with claim 1 of the present application.

Further, the Curtet patent simply discloses the use of an air-jet micronizer to co-micronize fenofibrate and a surfactant, principally sodium lauryl-sulfate. The aim of the Curtet patent in using this process is to improve the absorption of the active agent, thereby increasing its bioavailability (column 1, lines 30-34). In fact, the background discussion of the Curtet patent states that inclusion of a surfactant excipient is known to improve bioavailability (column 1, lines 30-34). The background discussion of the Curtet patent also states that micronising the active agent is known to improve biovailablity. This improvement results from increasing the surface area of the active, which increases the dissolution of the active in the in vivo environment (column 1, lines 28-30).

The purported invention of the Curtet patent is the finding that bioavailability can be further increased by co-micronizing the active and surfactant. The Curtet patent does not explain how this improvement is achieved, and certainly does not suggest that it results from a coating of the surfactant on the active, or the formation of a composite active-surfactant particle, wherein the additive coats the active. In fact, the formation of such a coating or composite would be contraindicated, as the active would then be shielded by the additive from the in vivo environment in which it needs to rapidly dissolve.

Accordingly, it is not correct to assume that co-micronisation using an air-jet micronizer as disclosed in the Curtet patent is a method in accordance with the present application, or which results in composite particles according to the present application: terms such as "micronisation" encompass a very large range of processes, and simply specifying or using "co-micronisation" would not, as one of skill in the art would know, inevitably result in the of one of the materials being processed attaching to one of the other materials being processed. This is because the technique of micronisation can be used for many different purposes, such as particle size reduction; creation of a homogenous mixture of particles; breaking up, or creating agglomerates of particles; or simply mixing ingredients together.

In view of the teaching in the Curtet patent that dissolution is improved by co-micronisation of the active with a surfactant, it is clear that the surfactant cannot be coating or

attaching to the active during the co-micronisation process, as this would delay dissolution of the active upon oral administration. The skilled reader would know this to be the case.

Accordingly, the Curtet patent does not teach a method for making composite active particles in accordance with the present invention, wherein the additive material coats the active particles.

Further to this, as the Curtet patent is solely concerned with the preparation of formulations for oral administration via gelatine capsules, the expertise of a skilled reader of the Curtet patent would lie in the area of formulations for oral administration. Such a person would know that oral formulations are entirely different, and have to meet entirely different requirements, to those which are intended to be delivered to the lung.

For example, the actives disclosed in the Curtet patent are not suitable for administration to the lung. Further to this, the Curtet patent discloses that the active, fenofibrate, is administered at a dose of about 200 mg per therapeutic unit (column 1, lines 50-51). This is far in excess of the amount of active agent that would be administered to the lungs, as demonstrated by the present application, which teaches administration of the active agent in doses of under 2mg (see, for example, page 32, line 26).

Furthermore, the surfactant ('additive') is, as discussed above, included in the formulations of the Curtet patent to improve the bioavailability of the active agent (column 1, lines 30-34). The Curtet patent provides no suggestion of how such a surfactant might behave if administered to the lung, or how it might influence the activity of any active agent with which it was delivered to the lung.

One of skill in the art reading the Curtet patent would therefore recognize that it would be neither safe nor practical to adopt the teaching in the Curtet patent and apply it to formulations for inhalation. To suggest otherwise is simply incorrect.

In addition, the use of an additive in the present application is to improve the fine particle dose (FPD) and fine particle fraction (FPF) of formulations expelled from an inhaler device (page 11, line 28, to page 12, line 2). The Curtet patent fails to consider the properties of the formulations disclosed therein which may influence their release from an inhaler. Nor does the Curtet patent suggest any benefit to the use of a surfactant other than its ability to improve absorption of the active. One of skill in the art reading the Curtet patent could not possibly anticipate, from the teaching therein, any benefit to the use of an additive material in a formulation for inhalation, even if the formulations of the Curtet patent were adapted for such a use.

It is therefore asserted that the subject matter of the claims of the present application is both novel and inventive over the disclosure in the Curtet patent.

In view of the above, Applicants respectfully request withdrawal of the rejection of claims 1, 16-24, 27, 29-32, and 41-42 under 35 U.S.C. § 102(b) as being anticipated by Curtet et al. and withdrawal of the rejection of claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Curtet patent.

Double patenting rejections

Claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 24, 27-29, and 31-33 of copending Application No. 10/433,072.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 33-35, 37, 39, 42-43, and 59-61 of copending Application No. 10/433,185.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1-2, 5, 7-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/552,326.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

Claims 1, 7-8, 11-16, 28, and 35-38 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, and 26 of copending Application No. 11/791,385.

Applicants respond that the filing of a terminal disclaimer will be considered upon notification that the pending claims are otherwise allowable.

CONCLUSION

Reconsideration of the present application is requested. This Response is being submitted in response to the Final Office Action dated March 30, 2010 in the above-identified application. Concurrently with this Response, Applicant submits a petition for a one-month extension of time for filing a response, along with the requisite fee. Therefore the time for filing a response to the March 30, 2010 Office Action is thereby extended to July 30, 2010, and this Response is being timely filed. If it is determined that any additional fee is due in connection with this filing, the Commissioner is authorized to charge said fees to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly requested.

Respectfully Submitted,
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